

**Amendments to the Drawings:**

The attached two sheets of replacement drawings include changes to original Figs. 8 and 14. The first replacement sheet includes Figs. 8 and the second replacement sheet includes Figs. 14A-14C. These sheets replace the original sheets including Figs. 8 and 14, respectively.

Attachment: Replacement Sheet

**REMARKS/ARGUMENTS**

Claims 1-49 are pending in the application. Applicants appreciate the Examiner allowing claims 1, 3, 4, 30-40, 42, 46, 48 and 49. Claims 2, 5-13, 15-29, 41 and 47 are rejected, and claim 14 was objected. The claims have been amended as noted in the preceding section. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

**Claim Rejections - 35 USC §112**

In an Office Action mailed November 28, 2007, (hereinafter "Office Action") claims 2, 9, 10, 24 and 47 were rejected under 35 USC 112(b) as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter in which the applicant regards as the invention. Applicants have amended these claims to distinctly claim the instant invention. Accordingly, Applicants believe these claims are in now condition for allowance.

**Objection - 35 USC §132**

The Office Action includes an objection to the Amendment filed September 05, 2007 (hereinafter "Amendment") under 35 USC 132(a) as allegedly introducing new matter into the disclosure. Amendments to a patent application that are fully supported in the application as filed are not new matter. Thus, disclosure contained in any one of the written description, claims, or drawings of the application as filed may be subsequently added by amendment to any other part of the application without introducing new matter. For example, if an original claim recites an element not disclosed elsewhere in the specification, the description may be amended to disclose the claimed element.

Applicants attach replacement sheets for Figure 8, 14B and 14C introduced in the above-identified Amendment. These drawings are submitted to meet the requirement that all claimed elements be illustrated. The Figures represent implementations well known to those of ordinary skill in the art. Support for Figure 8 can be found throughout the application as originally filed including page 14, paragraph [0072]. Support for Figure 14B (a fluid pre-biasing device) and Figure 14C (an electromagnetic pre-biasing device) as well as Figure 14A (a spring

pre-biasing device) can be found in allowed claim 3 and the application as originally filed including pages 3 and 9, paragraphs [0011] and [0051]-[0052], respectively.

**Claim Rejections - 35 USC §102**

Claims 5-13, 17, 18 and 20-25 were rejected under 35 USC 112(b) as allegedly being anticipated by Knodel et al., (U.S. Patent No. 6,447,524) (hereinafter "Knodel"). Applicants respectfully traverse.

Claim 5 recites an apparatus with a central member that permits the passage of a tissue-penetrating member. One leg is connected to the central member and is adapted to curl radially to increase a distal radius of the apparatus. The increasing distal radius restrains motion of the apparatus in a proximal direction.

The support, use and advantages of an apparatus with this type of tissue-penetrating member is found throughout the application as originally filed on April 12, 2004, (hereinafter "Application"), including on page 4, paragraphs [0012-0014], page 5 paragraph [0018] and Figures 1 and 4.

Under 35 USC § 102, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. MPEP 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicant respectfully submits that Knodel fails to teach each and every element of the claimed invention. For example, claim 5 recites "...straight leg member...is adapted to curl radially to produce an increase in distal radius of said apparatus, and wherein said increase is adapted to restrain motion of said apparatus..." (emphasis added). This not taught in Knodel.

Knodel teaches a fastener with ends (107) and (108) that expand sequentially into the tissue with the use of sliders (70). The first and second legs (110) and (111) expand outwardly within the shaft and are not deployed until after the shaft (92) has been withdrawn from the tissue. Thus it would be impossible for the motion of the apparatus taught by Knodel to be restrained by increasing the radius of the legs since the apparatus shaft and legs are completely disengaged from one another at the time of full deployment. [See Knodel Column 14,

line 60 through Column 15, line 67] Applicant discloses an expander (30) which is gradually retracted. This gradual retraction forces anchor (10) to partially expand. Eventually the legs of anchor 10 will fully expand (see Application page 13, paragraphs [0069-0071]). As recited in Claim 5, this increase restrains the motion of the apparatus in a proximal direction. As the legs curl inward, trauma to neighboring structures is reduced. Claim 5 has been amended in this regard to further identify and distinguish the instant application. Compare Knodel Figures 18-23 with Applicants Figures 6-7.

Independent claims 17 and 20 are allowable over Knodel for reasons similar to claim 5. Claims 6-13, 18 and 21-25 ultimately depend from claims 17 and 20, respectively, and are allowable for at least the reasons similar to claims 17 and 20.

Claims 5-13, 15-29 and 41 were rejected under 35 USC 112(b) as allegedly being anticipated by Frazier et al., (U.S. Patent No. 6,746,472) (hereinafter "Frazier"). Applicants respectfully traverse.

Referring to Figure 9, the deployment of the tissue anchors (90) taught by Frazier are presumably stabilized by bracing the hinges and angles of the proximal (70) and distal (72) sections of the closure catheter (38) against the tissue. Only the tissue fastener penetrates the target tissue. There is no tissue penetrating member to deliver the anchor as recited in Applicants' claim 5.

Furthermore, claim 5 recites: "an increase in distal radius" to restrain the motion of the apparatus and "a first substantively straight leg member" (emphasis added). This lies in stark contrast to the legs (94) on the Frazier anchor which curve outward from the anchor (90) prior to and throughout deployment. (Figure 4). In Figure 15, Frazier shows examples of several anchor or barb configurations whereby the barb may be formed from a hollow tube or cut from a flat sheet. This describes a static configuration that does not teach that the initially straight barbs curl radially outward when positioned in the tissue. The barbs of Frazier are apparently integrally preformed unlike the apparatus claimed in the instant application.

Independent claims 17 and 20 are allowable over Frazier for reasons similar to claim 5. Claims 6-13, 15-16, 18-19, 21-29 and 41 depend from claims 5, 17 and 20, respectively, and are allowable for at least similar reasons.

Claims 5-13, 15-18, 20-29 and 41 were rejected under 35 USC 112(e) as allegedly being anticipated by Evard et al., (U.S. Patent No. 6,616,675) (hereinafter "Evard"). Applicants respectfully traverse.

Applicant respectfully submits that Evard fails to teach each and every element of the claimed invention. Claim 5 recites "...leg member...is adapted to curl radially to produce an increase in a distal radius of said apparatus..."(emphasis added). Evard teaches a connecting portion that may be elastic, adjustable, telescoping, distensible or of accordion construction. [Column 3, lines 25-40] Evard teaches a device that includes a cylindrical tubular mid portion (38) and engagement members (20) that transition from a first to a second configuration via an "outwardly splayed" arrangement. [Column 2, lines 30-35] The configuration and deployment of the anchors disclosed in the instant application are clearly not anticipated by Evard.

To further distinguish Applicants invention, independent claims 17 and 20 have been amended. Independent claims 17 and 20 are allowable over Evard for reasons similar to claim 5. Claims 6-13, 15-16, 18-19, 21-29 and 41 ultimately depend from claims 5, 17 and 20, respectively, and are allowable for at least the reasons similar to their corresponding independent claims.

### CONCLUSION

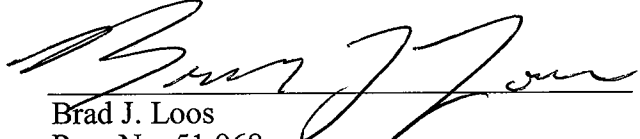
In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Appl. No. 10/822,138  
Amendment dated **May 28, 2008**  
Reply to Office Action of November 28, 2007

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

  
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Attachments - REPLACEMENT SHEETS OF DRAWINGS

BJL:bjl/nap  
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